

Québec, March 26, 2003

Mr. Stuart Shapiro  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm 1061  
Rockville, MD 20852

RE: Docket No. 02N-0278

Dear Mr. Shapiro:

These comments are in response to the FDA's requests for comments on rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Prior Notice of Imported Food)*

Le ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec (The department) feels that the FDA must achieve its counter-terrorism objective without making trade more restrictive than is necessary. The rule must therefore take into account the unique commercial environment present at the Canada-United States border, particularly as regards large volumes of just-in-time deliveries and perishable food products.

The department would reiterate the importance of establishing a minimum time for submitting prior notice that would strike a balance between the time required by the FDA and current trade practices for the large volumes shipped by truck or train. It is equally important that the requirements of the agents involved be consistent so as to avoid costly duplication and unnecessary interruptions in Canada/US trade.

The risk associated with Canada/US trade is reduced because many Canadian exporters are enrolled in programs such as *Customs-Trade Partnership Against Terrorism (C-TPAT)* and *Free and Secure Trade (FAST)*.

In view of this context, the department wishes to make the following comments on the proposed rule regarding mandatory submission of prior notice before shipping food products to the United States.

02N-0278

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Persons authorized to submit prior notice

When a Canadian commodity is exported to the United States, it is the Canadian merchant or exporter that knows with the highest degree of accuracy what the FDA needs to know. Since the law does not stipulate who is required to submit the prior notice, we therefore recommend that the regulation authorize the exporter to complete prior notice formalities.

Time at which prior notice must be submitted

If the requirement concerning the time at which prior notice must be submitted is maintained, all shipments from producers located near the border will be at a disadvantage. We recommend that the exporter be required to submit prior notice no later than eight hours before the projected time of arrival, and be authorized to submit amendments up to one hour before the projected time of arrival.

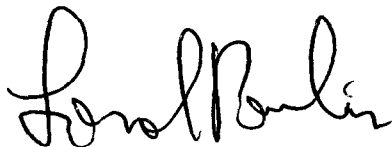
Content of amended prior notices

Since amendments for product quantity, format, or brand names have no bearing on the decision to ban product imports, we recommend that amendments be allowed to specify product identity, brand name, and quantity. Furthermore, we do not see the usefulness of providing an amendment notice as part of the initial notice.

Specifications as to the time of arrival

As for the time of arrival at Customs, the exporter can only provide an estimate. This factor is beyond the exporter's control since the carrier in turn is subject to various rules. In addition, unforeseen events such as accidents and Customs delays may cause late arrival. Consequently, we propose that exporters who choose to report to certain border crossings (to be identified) not be required to provide notification of lateness in the time of arrival at the border. These border crossings would be staffed with inspection personnel at all times.

Sincerely,

A handwritten signature in black ink, appearing to read 'Laval Poulin', with a stylized, cursive script.

Laval Poulin  
Director  
Trade Policy and Intergovernmental Affairs Division